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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/684,725      | 10/06/2000  | Lee Harland          | PCS10361ADAM        | 1550             |

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Gregg C Benson  
Pfizer Inc  
Patent Department MS  
8260-1611 Eastern Point Road  
Groton, CT 06340

EXAMINER

LI, RUIXIANG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/684,725

Applicant(s)

HARLAND, LEE

Examiner

Ruixiang Li

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9-12, 23-25, and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12, 23-25 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                               |                                                                             |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other:                                          |

## **DETAILED ACTION**

### **I. Status of Application**

Applicant's request filed in Paper No. 11 on December 16, 2002 for Continued Examination (RCE) under 37 CFR 1.111 has been approved. An action on the RCE follows.

### **II. Applicants' Amendment**

Applicants' amendment in Paper No. 12 filed on December 16, 2002 has been entered in full. Claims 6-8, 22, 26-31, and 33-36 have been canceled. Claims 10, 11, 23, and 32 have been amended. Claims 9-12, 23-25, and 32 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### **III. Withdrawn Objections and/or Rejections**

The rejection of claims 6-8, 22, 26-31, 33, and 34 under 35 U.S.C. 101 and 35 U.S.C. 112, 1<sup>st</sup> paragraph (utility related enablement), as set forth in the previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002), has been withdrawn in view of applicants' cancellation of the claims.

The rejection of claims 6-8, 23, 29, 31, and 34 under 35 U.S.C. 112, 1<sup>st</sup> paragraph for written description, as set forth in the previous Office Action (Paper No. 8,

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November 2, 2001 and Paper No. 10, June 10, 2002), has been withdrawn in view of applicants' cancellation of claims 6-8, 29, 31, and 34.

The rejection of claims 6, 7, 9, 23-27, 31, and 34 under 35 U.S.C. 102 (b) by Database accession No. AC008571, as set forth in the previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002), has been withdrawn in view of applicants' argument and cancellation of the claims 6, 7, 26, 27, 31, and 34.

The rejection of claims 7, 9-12, 22, 23, 29, 31, and 34 under 35 U.S.C. 102 (b) by Tan et al. as set forth in the previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002), has been withdrawn in view of applicants' cancellation of claims 22, 29, 31, and 34 and claim amendment.

#### **IV. Claims Rejections under 35 USC § 101**

The rejection of claims 9-12, 23-25, and 32 under 35 U.S.C. §101, as set forth in the previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002), remains. Claims 9-12, 23-25, and 32 are rejected under 35 U.S.C. §101 for the following reasons, as well as for the reasons set forth in the previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002).

Applicants argue that the polynucleotides sequences have utility as encoding neuromedin U receptors that bind neuromedin U. This has been fully considered but is not deemed persuasive because the disclosure fails to disclose a specific and substantial utility for the claimed polynucleotide sequences. It is unclear from the specification whether the neuromedin U receptors have a common use that one skilled

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in the art would immediately know what to do with the claimed polynucleotide sequences and how to use the claimed polynucleotide sequences.

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. The assertion that the polynucleotides sequences have utility as encoding neuromedin U receptors that bind neuromedin U does not endow the claimed molecules with a specific and substantial utility. In this regard, it is noted that Hosoya et al. (IDS, J. Biol. Chem., 275:29528-29532, 2000) teach the discrepancy in activities of neuromedin U and such discrepancy in activities of neuromedin might due to the existence of an unknown receptor subtype for neuromedin U (second column of page 29528). Hosoya et al. concluded with following statement on their study on TGR-1 and FM3, two receptors for neuromedin U: "Our results suggest that TGR-1 and FM-3 possess different distributions and functions among tissues in vivo. The discovery of neuromedin U receptor subtypes provides valuable insight into the physiological roles of neuromedin U and the identification of neuromedin U receptor agonists and antagonists." Thus, the mere assertion that the polynucleotides sequences of the present have utility as encoding neuromedin U receptors that bind neuromedin U is not sufficient to provide the knowledge of the biological and physiological functions and a specific and substantial utility or a well-established utility. No art of record discloses or suggests any property or activity for the claimed molecules such that another non-asserted utility would be well-established for the claimed invention.

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Claim 10 is also rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 10 recite "a host cell transformed or transfected with the polynucleotides of claim 23". Thus, the claim reads on a transgenic human, which is non-statutory subject matter. It is recommended that "a host cell" be replaced by "an isolated host cell" to overcome this rejection.

#### **V. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Enablement)**

The rejection of claims 9-12, 23-25, and 32 under 35 U.S.C. §112, 1<sup>st</sup> paragraph, as set forth in the previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002), remains.

Claims 9-12, 23-25, and 32 are rejected under 35 U. S. C. § 112, 1<sup>st</sup> paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention.

The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reasons set forth above.

Furthermore, even if the polynucleotides sequence of SEQ ID NO: 1 or encoding the polypeptide of SEQ ID NO: 2 were to have a patentable use, the instant disclosure would not be found to be enabling for an isolated or purified polynucleotide comprising a nucleotide sequence that has at least 95% identity to a polynucleotide of SEQ ID NO: 1 or encoding SEQ ID NO 2.

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Claim 23 has been amended to recite an isolated or purified polynucleotide comprising a polynucleotides comprising a nucleotide sequence that has at least 95% identity to a polynucleotide of SEQ ID NO 1 or encoding SEQ ID NO 2, or a polynucleotide encoding the polypeptide expressed by the DNA contained in the clone deposited as NCIMB 41066. Claims 9-12 depend upon claim 23. Applicants' amendment to claim 23 fails to overcome the rejection for the reasons set forth in previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002).

#### **VI. Claim Rejections Under 35 U. S. C. § 112, 1<sup>st</sup> Paragraph (Written Description)**

Claims 9-12 and 23 are rejected under 35 U.S.C. 112, 1<sup>st</sup> paragraph (Written Description). The basis for the rejection has been set forth in previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002).

Claim 23 has been amended to recite an isolated or purified polynucleotide comprising a polynucleotides comprising a nucleotide sequence that has at least 95% identity to a polynucleotide of SEQ ID NO 1 or encoding SEQ ID NO 2, or a polynucleotide encoding the polypeptide expressed by the DNA contained in the clone deposited as NCIMB 41066. Claims 9-12 depend upon claim 23. Applicants' amendment to claims fails to overcome the rejection for the reasons set forth in previous Office Action (Paper No. 8, November 2, 2001 and Paper No. 10, June 10, 2002).

## **VII. Claim Rejections Under 35 USC § 102**

The rejection of claim 12 under 35 U.S.C. 102 (b), as set forth in the previous Office Action (pages 14-15 of Paper No. 8, November 2, 2001 and page 8 of Paper No. 10, June 10, 2002), remains.

It is suggested that claim 12 be amended as "A membrane preparation of a recombinant host cell of claim 10 comprising the polypeptide of SEQ ID NO: 2".

## **VIII. Conclusion**

No. claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record




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includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li  
Examiner  
February 2, 2003

  
YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600